

### REMARKS

Claims 1-7, 12, 14, and 17 are amended. Claims 16, 22, and 24-28 are canceled. Claims 29 and 30 are added. Claims 1-14, 17, 29, and 30 are now pending in this application. The amendments to the claims are supported by the application as filed, and no new matter has been added.

The amendments to claims 1-7, 14, and 17 deleting the term "composition" and inserting the term "supplement" are supported by the specification as filed, for example, by originally-filed claims 1-7, 14, and 17.

The amendments to claims 1 and 17 inserting phrases relating to increasing the yield of breast meat from poultry are supported by the specification as filed, for example, by page 9, lines 2-5.

The amendments to claims 5 and 6 are supported by the specification as filed, for example by originally-filed claims 5 and 6, by page 8, lines 23-26, and by page 9, lines 24-27.

The amendment to claim 12 is supported, for example, by the specification as filed, for example, by page 5, lines 9-10.

New claims 29 and 30 are supported, for example, by the specification as filed, for example, by page 9, lines 1-5.

#### I. The Interview Summary

Applicants would like to thank Examiner Bertoglio for the courtesy extended during the telephonic interview on February 17, 2005. Applicants' attorney Peter Malen participated in the interview with Examiner Bertoglio.

The Office Action mailed September 01, 2004, the pending claims, and the cited art were discussed during the interview. Applicants indicated that in the Amendment and Response to the Office Action, they would include remarks distinguishing the pending claims from the cited art.

The above account is believed to be a complete and accurate summary of the interview as required by 37 C.F.R. § 1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicants respectfully request that the Examiner point out any deficiencies in her next communication so that Applicants can amend or supplement the interview summary.

## II. The Double Patenting Rejection

The Examiner rejected claims 1-4, 7-9, 11-14, 16 and 17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-8 of U.S. Patent No. 6,004,576 (hereinafter the '576 patent). Specifically, at page 3 of the pending Office Action, the Examiner alleges that it is inherent that the methods of the '576 patent will preferentially increase the yield of white meat from poultry. (emphasis added) Claim 16 has been canceled. As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

Independent claim 1 recites a method of increasing the yield of breast meat from poultry comprising: administering to poultry a supplement comprising animal plasma so as to increase the yield of breast meat from the poultry. Claims 2-4, 7-9, 11-14, and 17 depend either directly or indirectly from claim 1. Independent claim 29 recites a method of increasing the yield of breast meat and decreasing the yield of thigh and leg meat from poultry comprising administering to poultry a supplement comprising animal plasma so as to increase the yield of breast meat and decrease the yield of thigh and leg meat from the poultry.

In contrast, the '576 patent is directed to a method of increasing overall weight gain and improving feed efficiency of animals in the first stages of life. (*see* Claim 1) Specifically, claim 1 of the '576 patent recites a method of increasing weight gain and improving feed efficiency of animals in the first stages of life comprising: administering said animals a supplement consisting essentially of granulated animal plasma made by the process of: drying said animal plasma; compressing said dried animal plasma at about 1200-1400 psi; and screening said compressed dried animal plasma to form granulated particles; wherein each of the resulting granulated particles has a size greater than about 100 microns but less than about 2000 microns; and further providing that the bulk density of the granulated particles is about 50 pounds per cubic foot. Claims 2-4 and 6-8 of the '576 patent depend either directly or indirectly from claim 1. All of the working examples of the '576 patent disclose feeding the plasma product to pigs.

The Examiner alleges that it is inherent that the methods of the '576 patent will preferentially increase the yield of white meat from poultry. However, 35 U.S.C. §§ 100(b) and 101 clearly state that new uses of known compositions of matter are patentable subject matter. The independent claims of the instant application (*i.e.*, claims 1 and 29) recite new uses for known compositions of matter.

Further, a rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981); emphasis added. Further, "[t]hat which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *In re Spormann*, 363 F.2d. 444, 448 (C.C.P.A. 1966); emphasis added.

All of the working examples of the '576 patent disclose feeding a plasma product to pigs. Obviousness cannot be predicated on what is unknown. *Id.* Applicants respectfully submit that nothing in the '576 patent teaches or suggests that the administration of plasma would increase the yield of breast meat from poultry, much less that such a result would flow as a necessary conclusion from the teaching of the '576 patent. Thus, Applicants respectfully submit that the '576 patent does not teach or suggest a method of increasing the yield of breast meat from poultry comprising: administering to poultry a supplement comprising animal plasma so as to increase the yield of breast meat from the poultry (claim 1). Accordingly, the Examiner is respectfully requested to withdraw the obviousness-type double patenting rejection of the claims.

### III. The 35 U.S.C. § 112 First Paragraph Rejections

The Examiner rejected claims 1-14, 16, 17, 22 and 24-28 under 35 U.S.C. § 112, first paragraph, alleging that those claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 16, 22, and 24-28 are canceled. As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

The Examiner rejected claims 1-7, 14, 16, and 17, alleging that the term "composition" is new matter. Applicants respectfully disagree. However, to expedite prosecution, the pending claims are amended to recite the term "supplement", rather than "composition". The term "supplement" is found in originally-filed claim 1-7, 14, and 17. Claim 16 is canceled.

The Examiner rejected claim 1, 16, and 17, alleging that the term "preferentially increases the yield of white meat from poultry" does not find literal support in the specification. Applicants

respectfully disagree. However, to expedite prosecution, the pending claims are amended to recite that there is an increase in the yield of breast meat from the poultry. Claim 16 is canceled.

The Examiner alleges that the phrases "up to about 0.05-3.0%" and "up to about 0.1-1.5%" in claims 5 and 6 are new matter. However, the Examiner's attention is respectfully directed to originally-filed claims 5 and 6, which recite the same phrases. Thus, Applicants respectfully submit that those phrases are not new matter.

The Examiner also rejected claims 1-14, 16, 17, 22, and 24-28, alleging that to the extent that the claimed compositions and/or methods are not described in the instant disclosure, those claims do not enable one skilled in the art to make and/or use the invention. Applicants respectfully submit that the pending claims are described by the application as filed. Thus, withdrawal of this enablement rejection is respectfully requested.

The Examiner rejected claim 10 under 35 U.S.C. § 112, first paragraph, alleging that claim 10 contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner alleges that the specification fails to contemplate using a transgenic animal as a natural source of plasma. The Examiner's attention is respectfully directed to page 4, line 18 through page 5, line 6 of the application as filed, which discloses that the plasma may be collected by the art worker using methods known in the art from transgenic animals. The Examiner is also respectfully requested to note that the pending claims do not recite that a transgene would cause the plasma to be more effective. The claims only recite that the source of the plasma is a transgenic animal, and transgenic animals, including bovines, are now available to the art worker. Thus, Applicants respectfully submit that the specification enables obtaining plasma from transgenic animals.

Thus, it is submitted that the pending claims are in conformance with the requirements of 35 U.S.C. § 112, first paragraph. Therefore, withdrawal of the rejections of the claims under 35 U.S.C. § 112, first paragraph, is appropriate and respectfully requested.

#### IV. The 35 U.S.C. § 112 Second Paragraph Rejections

The Examiner rejected claims 1-14, 16, 17, 22, 27-28 under 35 U.S.C. § 112, second paragraph, alleging that those claims are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 16, 22, and 27-28 are canceled. As this rejection may be applied to the pending claims, it is respectfully traversed.

The Examiner rejected claims 1-4, 16, and 17, alleging that term "composition" is not clear. Applicants respectfully disagree. However, to expedite prosecution, the pending claims are amended to recite the term "supplement" rather than "composition". Applicants respectfully submit that the art worker, in possession of Applicants' specification, would readily understand the term "supplement" to refer to a dietary supplement. (*See Example 1*) Claim 16 is canceled.

The Examiner rejected claims 5, 6, 22, and 24, alleging that certain phrases reciting percentages by weight of water were not clear. Claims 22 and 24 are canceled. Claims 5 and 6 are amended, thereby rendering this rejection moot.

The Examiner also rejected claims 22, 27, and 28. Claims 22, 27, and 28 are canceled, thereby rendering this rejection moot.

Thus, it is submitted that the pending claims are in conformance with the requirements of 35 U.S.C. § 112, second paragraph. Therefore, withdrawal of the rejections of the claims under 35 U.S.C. § 112, second paragraph, is appropriate and respectfully requested.

#### V. The 35 U.S.C. § 102 Rejections

The Examiner rejected claims 1-4, 7-14, 16 and 17 under 35 USC § 102(b) as being anticipated by the '576 patent. Specifically, at page 9 of the pending Office Action, the Examiner alleges that it is inherent that the methods of the '576 patent will preferentially increase the yield of white meat from poultry. Claim 16 has been canceled. As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

35 U.S.C. §§ 100(b) and 101 clearly state that new uses of known compositions of matter are patentable subject matter. The independent claims of the instant application (*i.e.*, claims 1 and 29) recite new uses for known compositions of matter.

A rejection of anticipation under 35 U.S.C. § 102 requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Dillon*, 919 F.2d 688, 16

U.S.P.Q.2d 1897, 1908 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9<sup>th</sup> Cir. 1981). Moreover, an anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Applicants respectfully submit that the claims are not anticipated by the cited document.

The pending claims and the '576 patent are discussed in detail hereinabove in Section II (The Double Patenting Rejection).

The Examiner alleges that it is inherent that the methods of the '576 patent will preferentially increase the yield of white meat from poultry. However, a rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. (*Id.*)

All of the working examples of the '576 patent disclose feeding a plasma product to pigs. Applicants respectfully submit that nothing in the '576 patent teaches or suggests that the administration of plasma would increase the yield of breast meat from poultry, much less that such a result would flow as a necessary conclusion from the teaching of the '576 patent. Thus, Applicants respectfully submit that the '576 patent does not teach or suggest a method of increasing the yield of breast meat from poultry comprising: administering to poultry a supplement comprising animal plasma so as to increase the yield of breast meat and from the poultry. Accordingly, the Examiner is respectfully requested to withdraw this 35 USC § 102(b) rejection of the claims.

## VI. The 35 U.S.C. § 103 Rejection

The Examiner rejected claims 1-7, 10, 11, 13, 14, 16-18, 22, and 24-26 under 35 USC § 103(a) as being unpatentable over Adalsteinsson *et al.* (U.S. Patent No. 6,086,878; herein after the '878 patent). Specifically, at pages 10-11 of the Office Action, the Examiner alleges that the preferential increase in white meat as claimed in the instant invention is an inherent property of the methods taught by the '878 patent. Claims 16, 22, and 24-26 are cancelled. As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

35 U.S.C. §§ 100(b) and 101 clearly state that new uses of known compositions of matter are patentable subject matter. The independent claims of the instant application (*i.e.*, claims 1 and 29) recite new uses for known compositions of matter.

A rejection of obviousness under 35 U.S.C. § 103 requires that the Examiner establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the Examiner has the burden to establish three basic elements. First, the Examiner must establish that there is some suggestion or motivation, either in the cited documents themselves or in the knowledge generally available to an art worker, to modify the documents or to combine document teachings so as to arrive at the claimed invention. Second, the Examiner must establish that there is a reasonable expectation of success. Finally, the Examiner must establish that the prior art documents teach or suggests all the claim limitations. M.P.E.P. § 2143. Furthermore, "[t]hat which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *In re Spormann*, 363 F.2d. 444, 448 (C.C.P.A. 1966); emphasis added. Applicants respectfully submit that the claims are not *prima facie* obvious in view of the cited document because the cited document does not teach or suggest all of the claim limitations. Applicants also respectfully submit that the Examiner has not established that there is some suggestion or motivation, either in the cited documents themselves or in the knowledge generally available to an art worker, to modify the documents or to combine document teachings so as to arrive at the claimed invention.

The '878 patent is directed to methods of increasing muscle protein and/or reducing fat in an animal by administering antibodies to the animal. (column 2, lines 64-67; emphasis added) The '878 patent discloses that the antibody-producing animal preferably be "either be an egg-producing animal or a milk-producing animal and more preferably, an avian, ovine or a bovine. Avians, ovines and bovines are preferred because they produce an easily administered form of the antibody (*i.e.* the

milk or egg itself). As is well known to those having skill in the art, once an immune response is elicited, antibodies are produced and are transferred to the eggs or milk of the immunized avian or mammal. ... In addition to eggs and milk, antibodies can be obtained from whole blood, plasma or serum from any inoculated animal." (column 7, lines 23-42)

The '878 patent discloses that eggs or milk may be administered to animals because eggs and milk have high concentrations of the desired antibodies. (column 7, lines 23-42 and column 2, 37-51) Applicants respectfully submit that the art worker would not have been motivated to administer plasma to animals because the plasma would not have concentrations of the desired antibodies at the same concentration as would the eggs or milk. Thus, even if, for the sake of argument, the '878 patent suggests that antibodies may be obtained from plasma for administration, Applicants respectfully submit that nothing in the '878 patent teaches or suggests the direct administration of plasma. Applicants also respectfully submit that nothing in the '878 patent teaches or suggests that the direct administration of plasma would increase the yield of breast meat from poultry, much less that such a result would flow as a necessary conclusion from the teaching of the '878 patent.

Accordingly withdraw of the rejection of the claims under 35 U.S.C. § 103 is appropriate and is respectfully requested.



**CONCLUSION**

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is respectfully requested. The Examiner is invited to telephone Applicants' attorney at (612) 371-2110 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

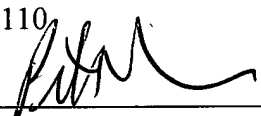
Respectfully submitted,  
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Date

February 28, 2005

By

  
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 28<sup>th</sup> day of February, 2005.

Name

Signature

Patricia A. H. Hmew

